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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,923	01/04/2002	Stephen Martone	501060.01	3782

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INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tath

Office Action Summary	Application No. 10/040,923	Applicant(s) MARTONE ET AL.	
	Examiner Jonathan ML Foreman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 and 53-58 is/are pending in the application.
 4a) Of the above claim(s) 3-6, 9, 11, 24, 26, 27, 29, 40 and 55-58 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 2, 7, 8, 10, 12-23, 25, 28, 30-39, 41-50, 53 and 54 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 7, 8, 19, 21, 34 - 38, 39, 48, 50, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido in view of U.S. Patent No. 5,337,734 to Saab.

In regards to claims 1, 2, 7, 8, 19, 21, 34 - 38, 39, 48, Shishido discloses a sheath assembly adapted for use with an endoscopic insertion tube including a sheath (Col. 6, lines 1 – 6) having a body portion adapted to partially encapsulate the working end of the insertion tube and having a distal end adapted to be proximate the working end when the sheath assembly is positioned on the insertion tube (Col. 6, lines 6 – 12); and a collection member attached to the sheath and including a collection member proximate the distal end portion (Col. 6, line 61 – Col. 7, line 9). The sampling device comprises a brush member (Col. 6, lines 31 – 40) and is attached to the body portion of the sheath. The brush member has a contoured shape and would partially conform to the curvature of the insertion tube because of the resilient nature of the bristles. The sheath has a channel extending longitudinally along part of the body portion and having an opening adapted to be proximate the distal end of the insertion tube when the sheath assembly is positioned on the insertion tube (Figure 6). The sheath is adapted to tightly surround a distal portion of the insertion tube. Shishido discloses a sheath assembly (Col. 6, lines 1 – 6) for use with an endoscope having an outer peripheral

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surface and a sampling device attached to the outer surface (Figure 6), but fails to disclose the sheath having an enclosed distal end to completely encapsulate the insertion tube. Saab teaches a sheath assembly for use with an endoscope having an enclosed distal end. It would have been obvious to one having ordinary skill in the art to modify the sheath as disclosed by Shishido to include an enclosed distal end as taught by Saab in order to eliminate problems of cleaning and sterilizing the endoscope between uses (Col. 1, lines 18 – 26).

In regards to claims 50, 53 and 54, Shishido discloses a method for obtaining a sample from a target within a body, the body being a tube or the like, including providing an endoscopic assemble including a sheath having a sampling device attached thereto (Col. 6, lines 1 – 6), the sampling device having a collection member proximate the distal end of the assembly; inserting the collection member into the body; engaging the collection member with the target; and removing the collection for the body (Col. 6, line 61 – Col. 7, line 9). The assemble comprises an insertion tube and at least part of the insertion tube is encapsulated by a sheath having the sampling device attached thereto (Figure 6). Shishido discloses the collection member being a brush (Figure 7). However, Shishido fails to disclose the sheath having an enclosed distal end to completely encapsulate the insertion tube. Saab teaches a sheath assembly for use with an endoscope having an enclosed distal end. It would have been obvious to one having ordinary skill in the art to modify the sheath as disclosed by Shishido to include an enclosed distal end as taught by Saab in order to eliminate problems of cleaning and sterilizing the endoscope between uses (Col. 1, lines 18 – 26).

3. Claims 1, 2, 7, 8, 19, 21, 34 - 38, 39, 48, 50, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,301,061 to Nakada et al. in view of U.S. Patent No. 5,337,734 to Saab.

In regards to claims 1, 2, 7, 8, 19, 21, 34, 35, 38, 39, and 48, Nakada et al. discloses a sheath (Figure 14) assembly adapted for use with an endoscopic insertion tube including a sheath (9) having a body portion adapted to partially encapsulate the working end of the insertion tube (2) and having a distal end adapted to be proximate the working end when the sheath assembly is positioned on the insertion tube; and a collection member (41) attached to the sheath and including a collection member proximate the distal end portion. The sampling device comprises a brush member and is attached to the body portion of the sheath (Col. 7, lines 5 – 12). The brush member has a contoured shape and would partially conform to the curvature of the insertion tube because of the resilient nature of the bristles. The sheath has a channel extending longitudinally along part of the body portion and having an opening adapted to be proximate the distal end of the insertion tube when the sheath assembly is positioned on the insertion tube (Col. 7, lines 13 – 16). The sheath is adapted to tightly surround a distal portion of the insertion tube. However, Nakada et al. fails to disclose the sheath having an enclosed distal end to completely encapsulate the insertion tube. Saab teaches a sheath assembly for use with an endoscope having an enclosed distal end. It would have been obvious to one having ordinary skill in the art to modify the sheath as disclosed by Nakada et al. to include an enclosed distal end as taught by Saab in order to eliminate problems of cleaning and sterilizing the endoscope between uses (Col. 1, lines 18 – 26).

In regards to claims 50, 53 and 54, Nakada et al. discloses a method for obtaining a sample from a target within a body, the body being turbine, boiler, engine or the like, including providing an endoscopic assemble including a sheath (9) having a sampling device (41) attached thereto, the sampling device having a collection member proximate the distal end of the assembly; inserting the collection member into the body; engaging the collection member with the target; and removing the collection for the body (Col. 7, lines 5 – 12). The assemble comprises an insertion tube and at least

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part of the insertion tube is encapsulated by a sheath having the sampling device attached thereto (Col. 7, lines 13 – 16). Nakada et al. discloses the collection member being a brush. However, Nakada et al. fails to disclose the sheath having an enclosed distal end to completely encapsulate the insertion tube. Saab teaches a sheath assembly for use with an endoscope having an enclosed distal end. It would have been obvious to one having ordinary skill in the art to modify the sheath as disclosed by Nakada et al. to include an enclosed distal end as taught by Saab in order to eliminate problems of cleaning and sterilizing the endoscope between uses (Col. 1, lines 18 – 26).

4. Claims 1, 2, 19 – 21, 34, 35 and 48 – 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,699,178 to Koda in view of U.S. Patent No. 5,337,734 to Saab.

In regards to claims 1, 2, 19 – 21, 34, 35, 48 and 49, Koda discloses a sheath assembly (Figure 5) adapted for use with an endoscopic insertion tube including a sheath having a body portion (50) adapted to partially encapsulate the working end of the insertion tube and having a distal end adapted to be proximate the working end when the sheath assembly is positioned on the insertion tube (Col. 4, lines 25 – 27); and a collection member (55) attached to the sheath and including a collection member proximate the distal end portion (Col. 4, line 45). The sheath has a channel (52) extending longitudinally along part of the body portion and having an opening adapted to be proximate the distal end of the insertion tube when the sheath assembly is positioned on the insertion tube. The sheath is adapted to tightly surround a distal portion of the insertion tube. Koda discloses an elastomeric body portion (Col. 4, line 32). However, Koda fails to disclose the sheath having an enclosed distal end to completely encapsulate the insertion tube. Saab teaches a sheath assembly for use with an endoscope having an enclosed distal end. It would have been obvious to one having ordinary skill in the art to modify the sheath as disclosed by Koda to include

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an enclosed distal end as taught by Saab in order to eliminate problems of cleaning and sterilizing the endoscope between uses (Col. 1, lines 18 – 26).

In regards to claims 50, Koda discloses a method for obtaining a sample from a target within a body including providing an endoscopic assemble including a sheath (50) having a sampling device (55) attached thereto, the sampling device having a collection member proximate the distal end of the assembly; inserting the collection member into the body; engaging the collection member with the target; and removing the collection for the body. The assembly comprises an insertion tube and at least part of the insertion tube is encapsulated by a sheath having the sampling device attached thereto (Col. 4, lines 32 – 45). However, Koda fails to disclose the sheath having an enclosed distal end to completely encapsulate the insertion tube. Saab teaches a sheath assembly for use with an endoscope having an enclosed distal end. It would have been obvious to one having ordinary skill in the art to modify the sheath as disclosed by Koda to include an enclosed distal end as taught by Saab in order to eliminate problems of cleaning and sterilizing the endoscope between uses (Col. 1, lines 18 – 26).

5. Claims 10, 12, 13, 16 – 18, 41 – 43, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido in view of U.S. Patent No. 5,337,734 to Saab as applied to claims 1 and 34 above, and further in view of U.S. Patent No. 6,551,278 to Geitz and U.S. Patent No. 5,899,850 to Ouchi.

In regards to claims 10, 12, 13, 16 – 18, 41 – 43, 46 and 47, Shishido in view of Saab discloses an endoscopic system having a collection member comprising a brush (Col. 6, liens 31 – 40), but fails to disclose a cover member being attached to the sheath and being movable between a first positioning at partially covering the collection member and a second position at least partially exposing the collection member. Shishido in view of Saab fails to disclose the cover member

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including an actuator extending along at least a part of the body portion, the actuator being moveably coupled in a first and second direction to the body portion for actuating the cover member. Geitz teaches an endoscopic system having a cover member (8) attached to the system and being movable between a first positioning at partially covering the distal tip and a second position at least partially exposing the distal tip. The cover member including an actuator (10) extending along at least a part of the body portion, the actuator being moveably coupled in a first and second direction to the body portion for actuating the cover member (Col. 6, lines 44 – 51).

Ouchi discloses an endoscopic system having a collection member comprising a brush (2). Ouchi discloses a cover member that surrounds the brush while it is not in use to protect the brush and any collected material (Col. 2, lines 4 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as disclosed by Shishido in view of Saab to include a moveable cover member as taught by Geitz in order to protect the brush and any collected material as taught by Ouchi (Col. 2, lines 4 – 10).

6. Claims 22, 23, 25, 28, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido in view of U.S. Patent No. 5,337,734 to Saab and further in view of U.S. Patent No. 6,551,278 to Geitz and further in view of U.S. Patent No. 5,899,850 to Ouchi.

In regards to claims 22, 23, 25, 28, 32 and 33, Shishido discloses a sheath assembly adapted for use with an endoscopic insertion tube including a sheath (Col. 6, lines 1 – 6) having a body portion adapted to partially encapsulate the working end of the insertion tube and having a distal end adapted to be proximate the working end when the sheath assembly is positioned on the insertion tube (Col. 6, lines 6 – 12); and a collection member attached to the sheath and including a collection member proximate the distal end portion (Col. 6, line 61 – Col. 7, line 9). The sampling

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device comprises a brush member (Col. 6, lines 31 – 40) and is attached to the body portion of the sheath. However, Shishido fails to disclose the sheath having an enclosed distal end to completely encapsulate the insertion tube. Saab teaches a sheath assembly for use with an endoscope having an enclosed distal end. It would have been obvious to one having ordinary skill in the art to modify the sheath as disclosed by Shishido to include an enclosed distal end as taught by Saab in order to eliminate problems of cleaning and sterilizing the endoscope between uses (Col. 1, lines 18 – 26). Additionally, Shishido fails to disclose a cover member being attached to the sheath and being movable between a first positioning at partially covering the collection member and a second position at least partially exposing the collection member. Shishido fails to disclose the cover member including an actuator extending along at least a part of the body portion, the actuator being moveably coupled in a first and second direction to the body portion for actuating the cover member. Geitz teaches an endoscopic system having a cover member (8) attached to the system and being movable between a first positioning at partially covering the distal tip and a second position at least partially exposing the distal tip. The cover member including an actuator (10) extending along at least a part of the body portion, the actuator being moveably coupled in a first and second direction to the body portion for actuating the cover member (Col. 6, lines 44 – 51). Ouchi discloses an endoscopic system having a collection member comprising a brush (2). Ouchi discloses a cover member that surrounds the brush while it is not in use to protect the brush and any collected material (Col. 2, lines 4 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as disclosed by Shishido in view of Saab to include a moveable cover member as taught by Geitz in order to protect the brush and any collected material as taught by Ouchi (Col. 2, lines 4 – 10).

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7. Claims 12 – 15, 41 and 43 - 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido in view of U.S. Patent No. 5,337,734 to Saab as applied to claims 1 and 34 above, and in view of U.S. Patent No. 5,603,699 to Shine.

In regards to claims 12 – 15, 41 and 43 – 45, Shishido in view of Saab discloses a sharp collection member (Col. 6, line 61 – Col. 7, line 5) but fails to disclose a cover member attached to the device proximate the collection member to at least partially cover the collection member. Shishido in view of Saab fails to disclose the cover member being movable between a first position partially covering the collection member, and a second position at least partially exposing the collection member. Shishido in view of Saab fails to disclose the cover member being hingeably attached to the device and biased into the first position. Shine discloses a hinged cover member for sharp collection members being positioned proximate the sharp member and movable between a first and second position covering and exposing the member respectively (Col. 2, line 65 – Col. 3, line 6). Shine discloses the cover member being biased into the first position (Col. 6, lines 5 – 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Shishido in view of Saab to include a cover member as taught by Shine in order to protect the user from accidental puncture (Col. 1, lines 5 – 10).

8. Claims 22, 25, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido in view of f U.S. Patent No. 5,337,734 to Saab and further in view of U.S. Patent No. 5,603,699 to Shine.

In regards to claims 22, 25, 30 and 31, Shishido discloses a sheath assembly adapted for use with an endoscopic insertion tube including a sheath (Col. 6, lines 1 – 6) having a body portion adapted to partially encapsulate the working end of the insertion tube and having a distal end adapted to be proximate the working end when the sheath assembly is positioned on the insertion

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tube (Col. 6, lines 6 – 12); and a collection member attached to the sheath and including a sharp collection member proximate the distal end portion (Col. 6, line 61 – Col. 7, line 9). However, Shishido fails to disclose the sheath having an enclosed distal end to completely encapsulate the insertion tube. Saab teaches a sheath assembly for use with an endoscope having an enclosed distal end. It would have been obvious to one having ordinary skill in the art to modify the sheath as disclosed by Shishido to include an enclosed distal end as taught by Saab in order to eliminate problems of cleaning and sterilizing the endoscope between uses (Col. 1, lines 18 – 26).

Additionally, Shishido fails to disclose a cover member attached to the device proximate the collection member to at least partially cover the collection member. Shishido fails to disclose the cover member being movable between a first position partially covering the collection member, and a second position at least partially exposing the collection member. Shishido fails to disclose the cover member being hingeably attached to the device and biased into the first position. Shine discloses a hinged cover member for sharp collection members being positioned proximate the sharp member and movable between a first and second position covering and exposing the member respectively (Col. 2, line 65 – Col. 3, line 6). Shine discloses the cover member being biased into the first position (Col. 6, lines 5 – 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Shishido in view of Saab to include a cover member as taught by Shine in order to protect the user from accidental puncture (Col. 1, lines 5 – 10).

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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